

REMARKS

Claims 1, 47-64, 70, 74-81, 74-81, 86-97, 99, 100, 103, 104 and 114-127 are currently active.

The Examiner has rejected Claims 47-50 and 52-56 under 35 U.S.C. 112 as being improperly dependent. These claims have been amended to be properly dependent.

Applicants have added a structural limitation for dynamically controlling the environment; the environment controlling means. Antecedent support for this limitation is found in canceled Claim 5.

The Examiner has rejected Claims 1, 47-64, 70, 74-81, 86-97, 99, 100, 103, 104 and 124-127 as being anticipated by Funakubo. Applicants respectfully traverse this rejection.

Referring to Funakubo, there is disclosed a cell selecting apparatus. Funakubo teaches the monoclonal antibody finds large fields of applications. However, the selection of desired cells or microorganisms resistant to the liquid culture of certain compositions from cells or microorganisms containing different kinds of cells or microorganisms is carried out

manually, but there are problems in that the probability that the desired monoclonal antibody producing cells can be obtained is low, in that the cells so obtained are highly unstable (that is, easy to be killed), and in that there is a great possibility that various germs may mix up during the selecting process. Therefore, when it comes to the selection of the cells capable of producing a great number of highly active monoclonal antibodies, the selection is required to start from a huge number of fused cells. Thus, in either case, increased manual labor and increased time are required. Furthermore, this type of selection requires a high level of technique, and in order to acquire this technique, a training period of normally one to two years is required and therefore the number of technicians qualified to perform the selection of the monoclonal antibody producing cells is very small. Because of that, the number of cells handled during a series of experiments is limited, and accordingly, the probability of the desired monoclonal antibody producing cells being obtained is low and even if they are obtained the capability of producing antibody is low.

Accordingly, Funakubo teaches its object is to minimize the manual intervention during the selection of the cell, thereby to minimize the possibility of the various germs being mixed during the selection process and to facilitate the efficient and stable selection of the cells. See column 3, lines 20-25. Furthermore, Funakubo teaches that the required labor can be considerably reduced and since the possibility of the various germs being mixed is eliminated, and the handling capacity can be increased, the selection of the desired cells can be

efficiently performed constantly at all times with the device taught by Funakubo. See column 4, lines 29-38.

Thus, to reiterate, the two paramount concerns of the device taught by Funakubo is to eliminate the manual operation that typically has been practiced previously and even more importantly, by eliminating the manual operation, eliminating the possibility of germs infecting and killing the monoclonal antibodies that are being studied.

Funakubo teaches an observatory section 24. Each well is inspected by a TV camera constituting the colony observation section 24, and by calculating the number and size of the colonies, the degree of proliferation is determined. See column 7, lines 30-34.

Claim 1 of applicants has the limitation that "each individual cell of the plurality of cells can be individually examined over time while the environment is dynamically controlled and maintained in the desired condition". It is respectfully submitted that Funakubo does not teach or suggest this limitation. Funakubo simply teaches that the observatory section 24 can be covered by an outer covering.

Funakubo teaches that the component parts, such as the observatory section 24 can be operated in a sterile environment while covered by an outer covering so as to permit

sterile air to be flowed there through. See column 7, lines 38-41. The outer covering in regard to sterile air follows from the primary purpose of Funakubo which is to prevent germs from contaminating the cells being studied. An outer covering that provides a sterile environment is a static environment, not a "dynamically controlled" environment. A sterile environment to protect the cells from germs is not a dynamically controlled environment. This is further emphasized by the fact that a complete review of Funakubo fails to teach or suggest any mechanism that can dynamically control the environment inside the outer covering and about the observatory section 24 unlike applicants' invention of Claim 1 which has an "environment controlling means." One skilled in the art would know that a outer covering to permit sterile air to be flowed there through is nothing at all like a dynamically controlled environment, especially since there is no teaching or suggestion, let alone any type of mechanism that would explain how such dynamic control can be achieved inside the outer covering taught by Funakubo. Accordingly, for this reason, Claim 1 is not anticipated by Funakubo and is patentable over Funakubo. It should be noted that applicants' definition of a dynamically controlled closed environment includes a biochamber or housing that has an opening or openings which allows the dynamically controlled internal environment to escape from the housing but not allow the external environment to the housing to enter through the opening or openings into the housing. Such a case could be where the pressure is maintained greater inside the housing than outside the housing so the internal environment would continuously flow out of the opening/openings. Thus, internally, the housing would only

experience the dynamically controlled environment since the environment is only flowing out of the housing and is thus closed to the external environment.

In addition, Claim 1 has the limitation that "each individual cell of the plurality of cells can be individually examined over time". Funakubo does not teach or suggest any capability of using the observatory section 24 or any other component to individually examine each individual cell of the plurality of cells over time. Funakubo specifically teaches it is concerned with tracking colonies of cells. The observatory section 24 taught by Funakubo is called the "colony" observatory section 24 which calculates the number and size of the colonies, to determine the degree of proliferation. Alternatively, Funakubo teaches the degree of proliferation may be determined by measuring the intensity of light transmitted through the solution. See column 7, lines 29-37. From these teachings, it is clear that Funakubo simply wants to know the overall growth of the colony and is not trying to individually examine each individual cell of the plurality of cells over time. It is respectfully submitted Funakubo has no consideration, nor capability of doing any individual examination of each individual cell, but is instead specifically teaching to produce large quantities of desired monoclonal antibodies and to produce the desired monoclonal antibody producing cells within one month. See column 4, lines 40-45 of Funakubo.

Accordingly, for this reason too, Claim 1 is patentable over Funakubo.

To reiterate, applicants' claimed invention is focused on examining individually over time each individual cell of a plurality of cells in a dynamically controlled environment because the environment and how it changes is also a very important factor in understanding an individual cell and what happens to it over time. In contradistinction, Funakubo is concerned with obtaining monoclonal antibodies, a process that requires colonies of cells to be grown, with the proliferation of the colony as a whole being of utmost concern.

Claims 47-50, 52-56, 94, 96, 103, 104, 124 and 125 are dependent to parent Claim 1 and are patentable for the reasons Claim 1 is patentable.

Claim 51 is patentable for the reasons Claim 1 is patentable. Claim 126 is dependent to parent Claim 51 and is patentable for the reasons Claim 51 is patentable.

Claim 57 is patentable for the reasons Claim 1 is patentable. Claims 58-64 and 127 are dependent to parent Claim 57 and are patentable for the reasons Claim 57 is patentable.

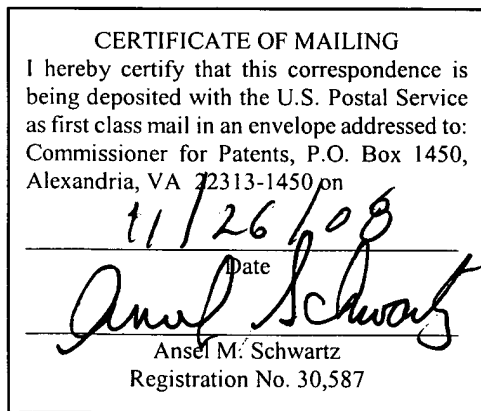
Claims 70, 74, and 75 are patentable for the reasons Claim 1 is patentable. Claims 76 and 79 are dependent to parent Claim 75 and are patentable for the reasons Claim 75 is patentable.

Claim 80 is patentable for the reasons Claim 1 is patentable. Claims 81, 86-93, 95, 97, 99 and 100 are dependent to parent Claim 80 and are patentable for the reasons Claim 80 is patentable.

Claim 114 is patentable for the reasons Claim 1 is patentable. Claims 115-123 are dependent to parent Claim 114 and are patentable for the reasons Claim 114 is patentable.

In regard to the double patenting rejection, applicants submit a double patenting terminal disclaimer to obviate this rejection.

In view of the foregoing amendments and remarks, it is respectfully requested that Claims 1, 47-64, 70, 74-81, 86-97, 99, 100, 103, 104 and 114-127, now in this application be allowed.



Respectfully submitted,

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